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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,517	10/16/2003	Amar Lulla	33396-198024	4905
26594	7590	06/09/2008		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 06/09/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/686,517

**Applicant(s)**

LULLA ET AL.

**Examiner**

MICAH-PAUL YOUNG

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 35-40, 44, 45, 74 and 75 is/are rejected.  
7) ☒ Claim(s) 22 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1-3,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44,45,74 and 75.

## **I DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/08 has been entered.

### ***Claim Objections***

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 1 recites that the film forming polymer is in a non-aqueous vehicle, while the dependent claim 22 recites that the vehicle can be water, a non aqueous solvent or a propellant. This claim is no longer consistent with the independent claim it depends from and does not further limit the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 34-50, 44, and 45 rejected under 35 U.S.C. 102(b) as being anticipated by Osipow et al (USPN 4,328,319 hereafter '319). The claims are drawn to a composition for topical application comprising at least one medicament, at least one film forming polymer, at least one vehicle and at least one of the following: at least one stabilizer, permeation enhancer, solubilizers, plasticizer and a water-soluble additive.

The '319 patent teaches a topical spray formulation containing an active agent, a film forming synthetic layer, a vehicle and other carriers, wherein the composition is made into a stable foam composition useful in external application (abstract, col. 11, lin. 57-col. 12, lin. 38). Regarding claims 2, 3, 12, 14, 15, 17-19 and 37-39, it is the position of the Examiner that the disclosures of the '319 patent anticipate the claims. The '319 patent teaches various medicaments such as steroids and hormones (hydrocortisone or testosterone) in a concentration from 0.02-15% (col. 12, lin. 1-38).

Regarding claims 1, 31, 32, 37, 40 and 45, it is the position of the Examiner that the disclosures of the '319 patent anticipates the claims. The '319 patent teaches film forming polymers (e.g. alkyl acrylate and alkyl methacrylate polymers and copolymers or ethyl cellulose), where the composition contains the said polymers up to 50% by weight (col. 8, lin. 54-col. 9, lin. 20 and lin. 64-66). Specifically Example 1 shows a formulation comprising 10.4% of film forming polymer ethyl methacrylate (example 1). The claims recite that the polymer is present in a concentration of about 0.0001 to about 10%. It is the position of the Examiner that 10.4% is well within the range of about 10%.

Regarding claims 6, 8, 10, 11, 20, 22, 23, 28, 29, 33, 35-37, 40 and 44 it is the position of the Examiner that the disclosures of the '319 patent anticipates the claims. The '319 patent teaches a permeation enhancers (e.g. surfactants or oleic acid, 0.0001-8%) (col. 7, lin. 5-31); plasticizers present in a concentration of 4.2 % (e.g. citrate esters such as tributyl citrate, 0.0001-10%) (col. 10, lin. 60-col. 11, lin. 11, example 1), propylene glycol (humectant), alcoholic vehicles, as well as non-aqueous solvents such as trichlorofluoromethane, ethanol acetone and methylene chloride, sodium lauryl sulphate as a solubilizer (col. 8, lin. 15-32, col. 7, lin. 6 and lin. 55-69, col. 10, lin. 52-59).

Regarding claims 25 and 26, which further limit the propellant, the '319 patent teaches a propellant at a concentration from 20-70% such as P114, P22 (col. 9, lin. 20-67 and col. 10, lin. 3-7).

Regarding the stable, breathable film limitation it is the position of Examiner that such limitations are inherently taught and possessed by the prior art product. The prior art teaches a topical sprayed composition comprising the same components in identical concentrations as the instant claims. The foams created by the '319 patent are stable and porous allowing for air transfer. Since the prior art teaches the same components combined in the same way in the same concentration, it remains the position of the Examiner that the composition of the '319 would inherently possess each and every property of the instant claims barring a showing to the contrary.

For these reasons at least the instant claims are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 35-40, 44, 45, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Osipow et al (USPN 4,328,319 hereafter '319) in view of Biedermann et al (USPN 5,980,921 hereafter '921). The claims are drawn to a composition for topical application comprising at least one medicament, one film forming polymer, in a non-aqueous vehicle and at least one component such as a plasticizer wherein the plasticizer is dimethyl isosorbide.

As discussed above the '319 patent discloses a composition comprising at least one medicament, one film forming polymer in a non aqueous vehicle and a plasticizer. The reference discloses several plasticizers such as tributyl citrate and other citrate esters, yet is silent to the specific plasticizer of claims 74 and 75. The inclusion of this well known plasticizer would be an obvious addition to the formulation as shown by the '921 patent.

The '921 patent teaches a topical composition comprising an active agents (present in a concentration from 3-5%), film-forming polymer (povidone) and vehicle (water) along with a plasticizer (dimethyl isosorbide) (from 5-20%) (Abstract, col.4, lin. 38-44, col. 5, lin. 20-25, 60-65, col. 9, lin. 29-44, and col. 10, lin. 17-25). The compositions are sprayed onto the skin and are intended to stay put providing a stable film that is water resistant (col. 14, lin. 30-38; examples). The active agents include anti-inflammatory agents such as hydrocortisone (col. 11, lin. 1-46). It would have been obvious to include the plasticizer of the '921 patent in to the formulation of the '319 since the formulation are similar in that they both form thin breathable films.

With these things in mind it would have been obvious to include the plasticizing solvent of the '921 patent into the formulation of the '319 patent in order to reduce tackiness and thus reduce the evenness of the sprayed film. One of ordinary skill in the art would have been motivated to make the simple substitution since the formulation are similar in composition and purpose, both delivering active agents topically via a sprayed film formulation comprising film forming polymers, vehicles and plasticizers, solvents and propellants. It would have been obvious to combine the teachings in the art with an expected result of a non-tacky drug delivery film that is breathable and stable.

#### ***Response to Arguments***

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive. Applicant argues that:

The newly amended claims that require a low concentration of the film forming polymer distinguish over the prior art.



Regarding this argument Applicant is direct to Example 1 of the '319 patent where ethyl methacrylate polymers is present as the film forming polymer in a concentration of 10.4 % while the plasticizer is present in a concentration of 4.2 %. The claims recite ranges that are *about* 0.0001% to *about* 10%. It remains the position of the Examiner that 10.4% is well within the range of "about"ne 10%. Applicant argues that the patent discloses that concentrations too low should be avoided, since the Films would be undesirable. The Examples show films formed from formulations comprising film forming polymers in concentration from 10.4-28.6%. The low end of these optimized Examples still meets the limitations of the claims. Regarding the breathable limitations, again it remains the position of the Examiner that such limitations are inherently met by the prior art. The '319 patent teaches a sprayable film composition comprising identical components in identical concentrations. Since a compound and its properties cannot be separated, any inherent properties would be present whether they were explicitly taught by the prior art or not. The films of the '319 patent are identical to those of the instant claims and as such must have each of the inherent properties such as being breathable and stable. For these reasons the claims remain rejected.

#### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
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/MICAH-PAUL YOUNG/  
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